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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,746	06/19/2000	Raymond J. Dattwyler	2631.1002-001	3998

21005 7590 02/10/2004

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/10/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/596,746

Applicant(s)

DATTWYLER ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 2October2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) 14-38 and 44-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13,39 and 41-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39,41-48 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicants' Response to Office Action, received 2 October 2003, is acknowledged. Claim 40 has been cancelled. Claims 1, 2, 8, 9, 10, 11, 39, 41, and 43 have been amended.

2. Claims 1-39 and 41-48 are pending. Claims 14-38 and 44-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Applicants elect SEQ ID NO:30 in response to the requirement for an election of species.

3. Claims 1-13, 39, and 41-43 are under consideration.

### Rejections Withdrawn/Moot

4. The rejection of claim 40 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein compositions comprising *B. burgdorferi sensu stricto* OspC proteins LipCB31, LipC12, UnlipC2, UnlipC2C7, UnlipC2C10, Unlip C2C12, UnlipC5C10, and UnlipC5C12, does not reasonably provide enablement for compositions comprising OspC from other *Borrelia*, or immunogenic fragments thereof, is moot in light of the cancellation of the claim.

5. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for "≥1 OspC polypeptide from each family", is withdrawn in light of the amendment of the claim.

6. The rejection of claim 43 under 35 U.S.C. 112, second paragraph, as being indefinite for "chimeric protein is SEQ ID NO:58 or SEQ ID NO:68", is withdrawn.

### Rejections Maintained

7. The rejection of claims 1-13, 39, and 41-43 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein compositions comprising *B. burgdorferi sensu stricto* OspC proteins LipCB31, LipC12, UnlipC2, UnlipC2C7, UnlipC2C10, Unlip

Art Unit: 1645

C2C12, UnlipC5C10, and UnlipC5C12, does not reasonably provide enablement for compositions comprising OspC from other *Borrelia*, or immunogenic fragments thereof, is maintained.

Applicants argue that the specification provides sufficient guidance and examples to support the recitation "immunogenic fragments thereof."

The examiner has considered applicants argument, but does not find it persuasive for the scope of the instant claims, i.e., any/all immunogenic fragments. While the instant specification does teach certain proteins LipCB31, LipC12, UnlipC2, UnlipC2C7, UnlipC2C10, UnlipC2C12, UnlipC5C10, and UnlipC5C12 as compositions for immunization of subjects and for diagnostic tests, the specification appears to be insufficient in determining which fragments are appropriate.

### Conclusion

8. Claims 1-13, 39, and 41-43 remain rejected.
9. This application contains claims 14-38 and 44-48 are drawn to an invention nonelected. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

Art Unit: 1645

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (571) 272-0865.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

February 9, 2004